

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on *** has been entered.

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed May 21, 2010. Claims 1-14 are pending in the application. Claim 1 has been amended. Claims 1-14 are being examined for patentability.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

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New Rejection(s) Necessitated by the Amendment filed on May 21, 2010

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,5,7,9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "they" in claim 1 lacks antecedent basis as 'they' implies a plural number of something but there is no prior plural number of elements. There is insufficient antecedent basis for this limitation in the claim. Claims 2,5,7,9 and 12 are rejected because they depend on rejected claim 1.

Examiner Note

The Examiner wants to point to Applicant that the claims should be self-consistent: independent claims begin with "A" and dependent claims begin with "The". Appropriate correction is recommended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerner et al. (US 2002/0168524 A1, previously cited in the Office Action on

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June 24, 2009) as evidenced by <http://medical-dictionary.thefreedictionary.com/silanization>

in view of Shimohata et al. (JP 2003292790 A, previously cited in the Office Action on June 24, 2009) and Anderson et al. (US Patent 6,521,668 B2, previously cited in the Office Action on June 24, 2009).

Applicant's Invention

Applicant claims surface-modified, pyrogenically produced zinc oxides, characterized in that they are aggregates and have the following physico-chemical characteristic data: BET surface areas of $18 \pm 5 \text{ m}^2 / \text{g}$ and C content of 0.5 to 1.0 wt. % wherein the surface modification includes silanization and the resultant modified surface is hydrophobic.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Kerner et al. teach surface-modified, doped, pyrogenically produced oxides such as zinc oxide (see [0005]) surface-modified with one or several organosilane compounds as disclosed in claim 2 of the instant application (see abstract and [0007-0118] of Kerner et al.). Kerner et al. teach a method of producing the surface-modified, pyrogenically produced oxides doped by aerosol, characterized in that the pyrogenically produced oxides are placed in a suitable mixing container, sprayed under intensive mixing, optionally with water and/or acid at first and subsequently with the surface-

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modification reagent or a mixture of several surface-modification reagents, optionally re-mixed for 15 to 30 minutes and are subsequently tempered at a temperature of 100 to 400 degrees Celsius for a period of 1 to 6 hours ([0119]). Further, Kerner et al. teach a production method for surface-modified, pyrogenically produced oxides doped by aerosol wherein the pyrogenically produced oxide starting material is mixed as homogeneously as possible with organohalosilanes under conditions, where oxygen is excluded, followed by a step where the mixture is heated with slight amounts of water vapor and optionally, in a continuous stream of inert gas in a treatment chamber designed as an upright tubular oven at temperatures of 200 to 800 degrees Celsius, preferably 400 to 600 degrees Celsius. The solid and gaseous reaction products are then separated from each other and, if necessary, the solid products are deacidified again and dried (see [0121]). Kerner et al. teach that the pyrogenically produced oxides doped by aerosol can be doped pyrogenically produced oxides of metals and/or metalloids in which the base components are oxides of metals and/or metalloids produced pyrogenically by flame hydrolysis wherein the BET surface of the doped oxides is between 5 and 600 m²/g ([0122]). Kerner et al. teach that it is possible with the method of their invention to dope all known, pyrogenically produced oxides (e.g., **zinc oxide**) with other metal oxides or metalloid oxides or their mixtures and that the **aggregate structure or agglomerate structure** of the pyrogenic oxide can be influenced by selecting suitable doping components ([0131-0132]). Kerner et al. additionally teach the use of the pyrogenically produced, surface-modified and doped oxides as UV blockers in cosmetics ([0145]).

With regards to the newly added limitation, “wherein the surface modification includes silanization and the resultant modified surface is hydrophobic”, thefreedictionary.com defines silanization as: **the chemical process of converting the SiOH moieties of a stationary form to the ester form**. Thus, it is the Examiner’s position that since Kerner et al. teach, a production method for surface-modified, pyrogenically produced oxides doped by aerosol wherein the pyrogenically produced oxide starting material is mixed as homogeneously as possible with organohalosilanes ([0121]), it is the Examiner’s position that this limitation is taught by Kerner et al.

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach a surface-modified zinc oxide that has an average diameter of 50 to 300 nm. This deficiency in Kerner et al. is cured by the teaching of Shimohata et al. Shimohata et al. teach a resin composition which is characterized by containing composite particle powder which has an average particle diameter of 0.01 to 10.0 microns and is prepared by coating the particle surfaces of zinc oxide particle powder with an organosilane compound (see PROBLEM TO BE SOLVED SECTION and abstract of Shimohata et al.).

The difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach a surface-modified zinc oxide having carbon content between 0.1-5 percent. This deficiency in Kerner et al. is cured by the teachings of Shimohata et al. Shimohata et al. teach the use of carbon black on a zinc

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oxide composite particle powder wherein the coating weight of said carbon black is 1-100% ([0013]).

The difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach a sunscreen preparation comprising the claimed surface modified zinc oxide wherein the sunscreen carrier is one such as ethylhexylmethoxycinnamate. This deficiency in Kerner et al. is cured by the teachings of Anderson et al. Anderson et al. teach the use of ethylhexylmethoxycinnamate as a carrier in a sunscreen preparation (see claims 1 and 8 of Anderson et al.).

The difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach that **a.)** The surface-modified zinc oxide aggregates have a shape factor F (circle) of below 0.5 and **b.)** The surface-modified zinc-oxide powder displays at its surface an oxygen concentration as non-desorbable moisture in the form of Zn-OH and/or Zn-OH₂ units of at least 40.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kerner et al. and Shimohata et al. to produce a topical sunscreen composition comprising surface-modified zinc oxides that has an

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average diameter of 50 to 300 nm and a carbon content between 0.1-5 percent.

Shimohata et al. teach that the addition of carbon black and an organosiloxane provides a composition having excellent mechanical strength, light resistance and ageing resistance (see PROBLEM TO BE SOLVED SECTION and abstract). One would have been motivated to make this combination in order to receive the expected benefit of having a sunscreen composition that contains particles having excellent mechanical strength, light resistance and ageing resistance.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kerner et al. and Anderson et al. to produce a topical sunscreen composition comprising surface-modified zinc oxides and ethylhexylmethoxycinnamate as a sunscreen carrier. Kerner et al. teach the use of the pyrogenically produced, surface-modified and doped oxides as UV blockers in cosmetics ([0145]) and Anderson et al. teach the use of ethylhexylmethoxycinnamate as a carrier in a sunscreen preparation (see claims 1 and 8 of Anderson et al.). Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two conventional sunscreen compositions set forth *prima facie* obvious subject matter.

In reference to the surface-modified zinc oxide aggregates having a.) a shape factor F (circle) of below 0.5 and b.) displaying at its surface an oxygen concentration as

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non-desorbable moisture in the form of Zn-OH and/or Zn-OH₂ units of at least 40%, In reference to **a.)**, Shimohata et al. teach that particle shape of zinc oxide particle powder may be in any shape, such as a globular shape, grain form, the shape of a polyhedron, a needle, a spindle shape, rice grain shape, flaky, scaly, tabular ([0017] of Shimohata et al.) and Kerner et al. teach that the aggregate structure or agglomerate structure of the pyrogenic oxide can be influenced by selecting suitable doping components ([0132]). Therefore, the shape factor as well as **b.)** the oxygen concentrations at the zinc oxide's surface are **physio-chemical properties** which are inherently possessed by the surface- modified zinc oxide, depending on the components used to modify the zinc oxide's surface and other physical factors. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Further, the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on April 13, 2010 with respect to the 103 rejection of claims 1-14 as being unpatentable over Kerner et al. (US 2002/0168524 A1) in view of Shimohata et al. (JP 2003292790 A) and Anderson et al. (US Patent 6,521,668 B2) have been fully considered but are moot in view of the new ground of rejection. However, the Examiner has addressed Applicant's arguments since the teachings of Kerner et al., Shimohata et al. and Anderson et al. have been used in the instant rejection.

Applicant argues that the combination of ZnO with any one of OC, OMC, PISA or BEMT produces synergistic results in terms of SPF (Sun Protection Factor) values (See pages 28-35) The Experiments compare the SPF values for ZnO alone, the OC, OMC, PISA or BEMT component alone, the combination, and in some cases include with the combination isostearic acid. Applicant presented a table that permits a quick

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comparison of SPF values. Applicant argues that it is clear from the Table that the SPF values for the combination of zinc oxide and the organic sun screen is more than a sum of the SPF values of the individual components. The Table also includes combinations of zinc oxide, the organic sunscreen and isostearic acid (IA), which have SPF values larger than the combination. Common to all the formulation is surface modified pyrogenically produced zinc oxide having a BET surface area of 18 4-5 mZ/g. The Examiner agrees with Applicant's conclusion that the data presented in the arguments filed on April 13, 2010 that the SPF values for the combination of zinc oxide and the organic sun screen is more than a sum of the SPF values of the individual components. However, instant claim 1 is drawn to a surface-modified pyrogenically produced zinc oxide powder. Thus the instant claims and the data presented in the tables and the instant claims are not commensurate in scope.

Applicant argues that the Office action focuses only on the surface modified product as set forth in claim 1 and the fortuitous mention of a less preferred BET range which includes the claimed BET values. Applicant argues that those BET values are for a surface modified doped metal oxide product, which is distinct from that claimed. However the Examiner disagrees with Applicant's arguments because Kerner et al. teach surface-modified, doped, **pyrogenically produced oxides** such as **zinc oxide** (see [0005]) **surface-modified with one or several organosilane compounds** as disclosed in claim 2 of the instant application (see abstract and [0007-0118] of Kerner et al.). Kerner et al. teach that the pyrogenically produced oxides doped by aerosol can

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be doped pyrogenically produced oxides of metals and/or metalloids in which the base components are oxides of metals and/or metalloids **produced pyrogenically by flame hydrolysis wherein the BET surface of the doped oxides is between 5 and 600 m²/g** ([0122]). Thus, the Examiner maintains that position that the BET values are for a surface modified doped metal oxide product, which is not distinct from that claimed.

Applicant argues that using Kerner et al.'s product as a starting point (educt) numerous selections (modifications) would need to have been made without any meaningful guidance except for Applicants' specification. The selections involve parameters which are critical to achieving the synergistic results shown in the specification. However, the Examiner disagrees with Applicant's assertion because the instant claims do not recite synergy. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the BET in Example 1, Table 2 is 36 m²/g and the instant claims recite 18± 5 m²/g. Thus, the inventive example does not meet the limitation of claim 1. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants' invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which

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does not exhibit an unexpected result (e.g., synergism) is therefore ipso facto unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed (e.g., BET surface area of $18 \pm 5 \text{ m}^2/\text{g}$), would have been obvious to one of ordinary skill having the above cited references before him

Applicant argues that Kerner et al. teaches a surface modified, pyrogenically produced oxide doped by aerosol. Numerous silanes are disclosed as surface modifying agents. See paragraphs [0006]- [0118]. Zinc oxide is mentioned as a candidate oxide but is not exemplified. However, the Examiner disagrees with Applicant's argument because when considering a prior art's teaching; the whole reference is considered, including the examples. Thus, the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

The claims remain rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney A. Brown whose telephone number is 571-270-3284. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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